

Remarks

A. Pending Claims

Claims and 35-38 are amended. Claims 39-43 are new. Claims 15-38 are pending.

B. Claim Rejections under 35 U.S.C. §102(b)

In the Office Action, claims 35-38 were rejected under 35 U.S.C. § 112 as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Office Action states:

Claims 35-38 positively recites parts supporting the vertebrae but the independent claims say "configured to support". Therefore, it is unclear if claims 35-38 are intended use recitations.
(Office Action, page 2)

By this response, claims 35-38 have been amended to further clarify certain features of the claims. Applicant submits that the amended claims are definite, and respectfully requests removal of the rejection under 35 U.S.C. § 112.

C. The Claims are Not Anticipated by Vaccaro under 35 U.S.C. §102(b)

In the Office Action, claims 15-17, 19-23, 25-29, and 32-34 were rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Pat. No. 6,102,950 to Vaccaro ("Vaccaro"). Applicant respectfully disagrees with these rejections for at least the following reasons.

The standard for "anticipation" is one of fairly strict identity. A claim can only be anticipated if each and every element set forth in the claims is found to be either expressly or inherently described in the cited art. *Verdegaal Bros. V. Union Oil Co. of California*, 814 F.2d 728, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987), MPEP §2131. "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970), MPEP 2143.03.

Independent Claim 15

Claim 15 describes a combination of features, including but not limited to:

an insert comprising a support surface for the second vertebra, the support surface configured to support the second vertebra above the superior surface of the cage element and inhibit movement of the second vertebra towards the first vertebra, wherein the insert is configured to be positioned at least partially in the cage element

Vaccaro does not appear to disclose at least the above quoted features in combination with other features of claim 15.

With respect to claim 15, the Office Action states:

Vaccaro discloses the following of the claimed invention: an intervertebral implant for a human spine, comprising: a cage element (20) with openings on its superior and inferior surfaces (please see Figure 2), and a side opening (70); first and second inserts (upper and lower elements 50); an expansion member (40); and a raised portion (52). Please also see col. 6, lines 27-41, and col. 7, lines 15-64. (Office Action, page 2)

Vaccaro discloses an intervertebral body fusion device having a wedge body, a cage component with a plurality of deployable spines having end plate penetrating teeth, and a contraction mechanism for drawing the wedge body into the cage component. (Vaccaro, abstract). In its final surgically-implanted position, the wedge body is substantially fully drawn within the cage component, resulting in a full deployment of teeth and associated spines into the adjacent end plates of the vertebral bodies. (Vaccaro, abstract). A cage component 20 includes a rigid upper member 22 defining a bearing surface 22a and an opposing interior surface 22b, and, a rigid lower member 24 also defining both a bearing surface 24a and an opposing interior surface 24b. (Vaccaro, col. 5, lines 32-35). The cage includes spines 50 integrally formed to depend from either an upper member 22 or a lower member 24. (Vaccaro, col. 6, lines 37-39). Each spine 50 has at least one tooth 52 facing outwardly at the free end 54, the tooth preferably forming a penetrating tip or spike. (Vaccaro, col. 6, lines 39-41). During use, each tooth 52 is fully deployed beyond an associated bearing surface 22a, 24a. (Vaccaro, col. 7, lines 28-29). Accordingly, Vaccaro appears to disclose teeth that are deployed beyond bearing surfaces such that the teeth penetrate into adjacent endplates of vertebral bodies. The bearing surfaces appear to be a fixed portion of the cage. Vaccaro does not, however, disclose a support surface configured to support a vertebra above a superior surface of the cage element. Accordingly,

Vaccaro does not appear to disclose at least the feature of, "an insert comprising a support surface for the second vertebra, the support surface configured to support the second vertebra above the superior surface of the cage element and inhibit movement of the second vertebra towards the first vertebra, wherein the insert is configured to be positioned at least partially in the cage element," in combination with other features of the claim.

The Office Action also states:

Please note that claim language such as "adapted to/for" and "configured to/for" is functional language. In order to be given patentable weight, a functional recitation must be supported by recitation in the claim of sufficient structure to warrant the presence of the functional language.
(Office Action, pages 2-3)

Applicant submits that the above-quoted features of claim 15 includes, "an insert comprising a support surface for the second vertebra." At least the inclusion of the "support surface for the second vertebra" provides sufficient structure for the subsequent feature of "configured to support the second vertebra above the superior surface of the cage element and inhibit movement of the second vertebra towards the first vertebra." Applicant respectfully submits that the above quoted feature of claim 15 should be given patentable weight.

For at least these reasons, Applicant submits that claim 15 is allowable over the cited art.

Independent Claim 21

Claim 21 describes a combination of features, including but not limited to:

an insert comprising an inferior surface and a support surface for the second vertebra, the support surface configured to support the second vertebra above the superior surface of the cage element and inhibit movement of the second vertebra towards the first vertebra, wherein the insert is configured to be positioned in the cage element such that the inferior surface of the insert is inside of the cage element and the support surface of the insert is outside of the cage element

For at least the reasons discussed above with respect to claim 15, Applicant submits that claim 21 is allowable over the cited art. Moreover, Applicant submits that Vaccaro does not

appear to disclose the feature of, “wherein the insert is configured to be positioned in the cage element such that the inferior surface of the insert is inside of the cage element and the support surface of the insert is outside of the cage element,” in combination with other features recited by claim 21.

For at least these reasons, Applicant submits that claim 21 is allowable over the cited art.

Independent Claim 27

Claim 27 describes a combination of features, including but not limited to:

- an expansion member configured to be inserted in a third opening in the cage element to raise a support surface of the first insert relative to the inferior surface of the cage element, wherein the support surface of the first insert is configured to couple to a first vertebra to support the first vertebra away from the cage element and inhibit movement of the first vertebra towards a second vertebra; and
- wherein the expansion member when inserted in the third opening is configured to raise a support surface of the second insert relative to the superior surface of the cage element, wherein the support surface of the second insert is configured to couple to the second vertebra to support the second vertebra away from the cage element and inhibit movement of the second vertebra towards the first vertebra.

For at least the reasons discussed above with respect to claim 15, Applicant submits that claim 27 is allowable over the cited art. For example, Vaccaro does not disclose at least the feature including, “wherein the support surface of the first insert is configured to couple to a first vertebra to support the first vertebra away from the cage element and inhibit movement of the first vertebra towards a second vertebra,” and “wherein the support surface of the second insert is configured to couple to the second vertebra to support the second vertebra away from the cage element and inhibit movement of the second vertebra towards the first vertebra,” in combination with the other features recited by claim 27.

For at least the reasons, Applicant submits that claim 27 is allowable over the cited art.

D. The Claims Are Not Obvious over Vaccaro in view of Sertich under 35 U.S.C. §103(a)

In the Office Action, claims 18, 24, 30, and 31 were rejected under 35 U.S.C. 103(a) as being unpatentable over Vaccaro in view of U.S. Pat. No. 5,800,550 to Sertich ("Sertich"). Applicant respectfully disagrees with this rejection for at least the following reasons.

To reject a claim as obvious, the Examiner has the burden of establishing a *prima facie* case of obviousness. *In re Warner et al.*, 379 F.2d 1011, 154 USPQ 173, 177-178 (C.C.P.A. 1967). To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 U.S.P.Q. 580 (C.C.P.A. 1974), MPEP §2143.03.

Applicant respectfully submits that in addition to being patentable based on claims 15, 21 and 27 from which they depend, claims 18, 24, 30 and 31 are patentable for certain features recited by each of the claims. Claims 18, 24, 30, and 31 each recite a combination of features including, but not limited to, a support surface of the insert comprising "osteoconductive mesh structure."

The Office Action states:

Vaccaro teaches the invention substantially as claimed, however, Vaccaro does not teach an osteoconductive mesh structure on the insert's support surface. Sertich teaches an intervertebral implant with an osteoconductive mesh structure in col. 4, lines 17-21 for the purpose of promoting bone ingrowth and fusion. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Vaccaro to include an osteoconductive mesh in order to promote bone ingrowth and fusion.
(Office Action, page 3)

The cited portion of Sertich states:

Yet an additional advantage of the present invention is the provision of an insertion tool which can be removed providing an interbody fusion cage which has hollow areas that can be packed with autologous cancellous bone or other material to promote bone ingrowth and fusion.
(Sertich, col. 4, lines 17-21)

Sertich discloses providing autologous cancellous bone packed in a hollow area of a fusion cage. Sertich does not disclose at least the feature of, a “support surface” of the insert comprising an “osteoconductive mesh structure,” in combination with other features of the claims.

For at least these reasons, Applicant submits that claims 18, 24, 30 and 31 are patentable over the cited art.

E. The Claims Are Not Obvious over Vaccaro under 35 U.S.C. §103(a)

In the Office Action claims 35-38 were rejected under 35 U.S.C. 103(a) as being unpatentable over Vaccaro. Applicant respectfully disagrees with this rejection for at least the following reasons.

If the proposed modification or combination would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 U.S.P.Q. 1125 (Fed. Cir. 1984); *see* M.P.E.P. § 2143.01(V).

Claims 35-38

Applicant respectfully submits that in addition to being patentable based on claims 15, 21 and 27 from which they depend, claims 35-38 are patentable for certain features recited by each of the claims.

With respect to claims 35-38, the Office Action states:

Vaccaro discloses the claimed invention except for the support surface covering a majority of the implant. It would have been an obvious matter of design choice to make the support surface cover a majority of the implant, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

(Office Action, page 3)

Applicant respectfully disagrees with the position that making the support surface cover a majority of the implant would have been an obvious design choice. As discussed above with respect to claim 15, the only portion of the cage of Vaccaro that appears to move relative to the cage and extended beyond the bearing surfaces includes a spine 50 having teeth 52. First, Applicant notes that the spine and teeth are not analogous to the claimed support surfaces, and, in sharp contrast, they are used to penetrate the adjacent bone. Second, Applicant submits that even if the spine and teeth were assumed to be analogous to a claimed feature for the sake of argument, increasing the area of the teeth and/or the inserts 50 would render the insert and the teeth unsatisfactory for their intended purpose of penetrating into adjacent endplates of vertebral bodies. Vaccaro explicitly states, that “[e]ach spine 50 has at least one tooth 52 facing outwardly at the free end 54, the tooth preferably forming a penetrating tip or spike.” (Vaccaro, col. 6, lines 39-41). Accordingly, the proposed modification of make making the support surface cover a majority of the implant would be contrary to a design for enabling the teeth to penetrate the bone, as a larger size could prevent penetration of the bone. Such a modification would render the spine and teeth unsuitable for their intended purpose, and thus there is no suggestion or motivation to make the proposed modification.

For at least these reasons Applicant submits that claims 35-38 are patentable over the cited art.

F. New Claims

New claim 39 recites a combination of features including, “a first member comprising a first inferior surface and a first superior surface, where the first superior surface comprises a substantially planar surface configured to contact and support a first vertebrae of a human spine; a second member comprising a second inferior surface and a second superior surface, where the second inferior surface comprises a substantially planar surface configured to contact and support a second vertebrae of a human spine; and an expansion element configured to be inserted between the first inferior surface and the second superior surface of after insertion of the first member and the second member in the human spine, wherein insertion of the expansion member is configured to expand the first and second members relative to one another to increase a

separation distance between the first superior surface and the second inferior surface.” Applicant submits that at least these features, in combination with other features of the claim, are not taught or suggested by the prior art.

New claim 40 recites a combination of features including, “further comprising a cage having first opening through which the first member is configured to expand, a second opening through which the second member is configured to expand, a third opening through which the expansion element is configured to be inserted, wherein the first and second openings are located on opposite sides of the cage.” Applicant submits that at least these features, in combination with other features of the claim, are not taught or suggested by the prior art.

New claim 41 recites a combination of features including, “wherein the support surface comprises a substantially planar surface configured to contact the second vertebra.” Applicant submits that at least these features, in combination with other features of the claim, are not taught or suggested by the prior art.

New claim 42 recites a combination of features including, “wherein the support surface comprises a substantially planar surface configured to contact the second vertebra.” Applicant submits that at least these features, in combination with other features of the claim, are not taught or suggested by the prior art.

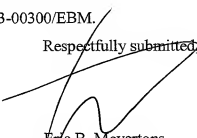
New claim 43 recites a combination of features including, “wherein the support surface of the first insert comprises a substantially planar surface configured to contact the first vertebra, and wherein the support surface of the second insert comprises a substantially planar surface configured to contact the second vertebra.” Applicant submits that at least these features, in combination with other features of the claim, are not taught or suggested by the prior art.

G. Additional Comments

Applicant submits that all claims are in condition for allowance. Favorable consideration is respectfully requested.

Authorization for an extension of time, excess claims fees, and the fee for a Request For Continued Examination will be made upon electronic submission of this document. If any other fees are required, please appropriately charge those fees to Meyertons, Hood, Kivlin, Kowert & Goetzel, P.C. Deposit Account Number 50-1505/5943-00300/EBM.

Respectfully submitted,



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